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Revised Dates: July 8, 2020; July 10, 2019
January 9, 2019; October 10, 2018; October 12, 2016;
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April 10, 2013; April 11, 2012; January 12, 2011; October 13, 2010

CRITERIA FOR PRIOR AUTHORIZATION

Botulinum Toxins

BILLING CODE TYPE For drug coverage and provider type information, see the [KMAP Reference Codes webpage](#).

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

OnabotulinumtoxinA (Botox®)
AbobotulinumtoxinA (Dysport®)
RimabotulinumtoxinB (Myobloc®)
IncobotulinumtoxinA (Xeomin®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.

CRITERIA FOR ONABOTULINUMTOXINA: (must meet one of the following):^{1,2}

- For Pprophylaxis of headaches in patients with chronic migraines, refer to the migraine prophylaxis agents PA criteria.^{3,4}
 - ~~○ Chronic migraine: 15 or more headache days per month, for more than three months, which, on at least 8 days/month, has the features of migraine headache.⁴~~
 - ~~○ Patient must have experienced an inadequate response after a trial of at least one agent from each medication class listed in Table 2 at a maximum tolerated dose, OR have a documented intolerance or contraindication to all preventive therapies.~~
 - ~~○ Prescriber must provide chart notes documenting the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials.~~
 - ~~○ Must be prescribed by or in consultation with a neurologist.~~
 - ~~○ Must not be used in conjunction with a CGRP antagonist.~~
- Treatment of upper limb spasticity in elbow, wrist, finger, or thumb flexors.
 - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of lower limb spasticity in ~~adult~~ patients to decrease the severity of increased muscle tone in ankle or toe flexors.
 - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of cervical dystonia.
 - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
 - Must be prescribed by or in consultation with a dermatologist.

- Prescriber must provide ~~chart notes documenting details of~~ the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials.
- Treatment of blepharospasm associated with dystonia or strabismus.
 - Must be prescribed by or in consultation with a neurologist or ophthalmologist.
- Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency or urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g., spinal cord injury or multiple sclerosis).
 - Patient must have experienced an inadequate response after a 30-day trial of at least 2 anticholinergics at a maximum tolerated dose, OR have a documented intolerance or contraindication to therapy with anticholinergic medications.
 - Must be prescribed by or in consultation with a neurologist or urologist.
 - Prescriber must provide ~~chart notes documenting details of~~ the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials.

CRITERIA FOR RIMABOTULINUMTOXINB: (must meet all of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Must be being used for one of the following:^{1,3}
 - Treatment of cervical dystonia.
 - Treatment of chronic sialorrhea in adults.

CRITERIA FOR ABOBOTULINUMTOXINA: (must meet all of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist
- Must be being used for one of the following:^{1,4}
 - Treatment of cervical dystonia.
 - Treatment of upper limb spasticity.
 - Treatment of lower limb spasticity.

CRITERIA FOR INCOBOTULINUMTOXINA: (must meet one of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist (or ophthalmologist for blepharospasm).
- Must be being used for one of the following:^{1,5}
 - Treatment of cervical dystonia.
 - Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA.
 - Treatment of upper limb spasticity.
 - Treatment of chronic sialorrhea in adults.

LENGTH OF APPROVAL (INITIAL): 6 months. Subsequent authorizations will be granted for up to 2 injections in 6 months; injections must be at least 12 weeks apart, unless otherwise specified in Table 1.

CRITERIA FOR RENEWAL: (must meet all of the following)

- Subsequent authorizations will be granted for up to 2 injections in 6 months.
- Injections must be at least 12 weeks apart, unless otherwise specified in Table 1.
- ~~The patient must meet one of the following for migraines:~~
 - ~~The patient has experienced a reduction in the number of monthly headache days compared to baseline (prior to starting treatment with the requested agent)~~
 - ~~Re-initiation for chronic migraines, if reverting from other step therapies, must meet all of the following:~~

- ~~Must discontinue CGRP antagonists for at least 30 days from last dispensing (90 days from last dispensing if a quarterly dosing was used).~~
- ~~Must discontinue topiramate extended release for at least 30 days (90 days from last dispensing if a 90-day supply was used).~~

LENGTH OF APPROVAL (RENEWAL): 12 months

Notes: Use of Botulinum Toxins will **NOT** be approved for cosmetic purposes.

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for botulinum toxins. ⁻⁶²⁻⁵

Agents	Indication(s)	Age	Dosing Limits
OnabotulinumtoxinA (Botox)	Chronic migraines	≥18	Up to 155 units every 12 weeks.
	Adult U pper limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	Pediatric upper limb spasticity	≥2 to 17 years	6 Units/kg or 200 Units, whichever is lower.
	Adult L ower limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	Pediatric lower limb spasticity, excluding spasticity caused by cerebral palsy	≥2 to 17 years	8 Units/kg or 300 Units, whichever is lower.
	Cervical dystonia	≥18 years	Up to 300 units every 12 weeks.
	Severe axillary hyperhidrosis	≥18 years	Up to 100 total units every 28 weeks.
	Blepharospasm	≥12 years	Up to 200 total units every 12 weeks.
	Strabismus	≥12 years	Up to 300 total units every 24 weeks.
	Overactive bladder	≥18 years	Up to 100 units every 24 weeks.
	Detrusor overactivity	≥18 years	Up to 200 units every 42 weeks.
RimabotulinumtoxinB (Myobloc)	Cervical dystonia	≥18 years	Up to 5,000 units every 12 weeks.
	Chronic sialorrhea	≥18 years	Up to 3,500 units every 12 weeks.
AbobotulinumtoxinA (Dysport)	Cervical dystonia	≥18 years	Up to 1,000 units every 12 weeks.
	Adults U pper limb spasticity	≥18 years	Up to 1,000 units every 12 weeks.
	Pediatric upper limb spasticity, excluding spasticity caused by cerebral palsy	≥2 to 17 years	16 Units/kg or 640 Units, whichever is lower.
	Lower limb spasticity	≥18 years	Up to 1,500 units every 12 weeks.

	Lower limb spasticity	≥2 <u>to 17 years</u>	<u>Up to 1,000 units every 12 weeks. 15 Units/kg for unilateral lower limb injections, 30 Units/kg for bilateral injections, or 1000 Units, whichever is lower.</u>
IncobotulinumtoxinA (Xeomin)	Cervical dystonia	≥18 <u>years</u>	Up to 120 units every 12 weeks.
	Blepharospasm	≥18 <u>years</u>	Up to 100 units (<u>50 units per eye</u>) every 12 weeks.
	Upper limb spasticity	≥18	Up to 400 units every 12 weeks.
	Chronic sialorrhea	≥18	Up to 100 units every 16 weeks.

Table 2. Prior Preventative Migraine Therapies.³

Beta-blocking Agents	Antiepileptic Agents
Propranolol	Topiramate
Metoprolol	Valproic acid
Timolol	Divalproex

References

1. ~~Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38:1-211. Available at <https://ichd-3.org/>. Accessed 6/19/19.~~
2. ~~1. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86 (19): 1818-26. Available at <https://www.aan.com/Guidelines/home/GuidelineDetail/735>. Accessed 6/18/196/3/20.~~
3. ~~Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-45. Available at <https://www.aan.com/Guidelines/home/GuidelineDetail/536>. Accessed 6/18/19.~~
4. ~~2. Botox (onabotulinumtoxinA) [package insert]. Madison, NJ: Allergan USA, Inc.; May 2018.~~
5. ~~3. Myobloc (rimabotulinumtoxinB) [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; May 2019.~~
6. ~~4. Dysport (abobotulinumtoxinA) [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; November 2018.~~
7. ~~5. Xeomin (incobotulinumtoxinA) [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; May 2019.~~

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